

Appl. No. 10/825,250  
Amdt. dated June 28, 2006  
Reply to Office Action of March 23, 2006

### REMARKS

Applicants have received and carefully reviewed the Office Action mailed March 23, 2006. Claims 30-45 remain pending. Reconsideration and reexamination are respectfully requested.

#### Rejection under 35 U.S.C. § 103(a)

Claims 30-45 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Kramer, Sirhan et al., and/or Euteneuer et al., in view of Ferguson et al. The Examiner asserts that Kramer, Sirhan et al. and Euteneuer et al. disclose a catheter having a lumen and guidewire lumen adapted to allow a guidewire disposed therein to be moved laterally out of the guidewire lumen from a first location proximal of the distal end of the cannula to the distal end of the cannula. The Examiner acknowledges that none of the cited references teach a second lumen in addition to the first lumen and the guidewire lumen. However, the Examiner asserts that duplication of a well-known element of an apparatus such as a lumen should not be considered patentable weight to a claim. The Examiner cites Ferguson et al. for teaching that catheter designs having three lumens are well-known in the art.

The Examiner also asserts that the apparatuses disclosed by Kramer, Sirhan et al., and Euteneuer et al. have structures that would allow a guidewire disposed in a lumen to be moved laterally out of said lumen, thus the capability to allow a guidewire to be moved laterally is inherent to the apparatuses. Applicants respectfully traverse the rejection.

It appears the Examiner has not considered the claimed element of the guidewire lumen being adapted to allow a guidewire disposed therein to be moved laterally out of the guidewire lumen from a first location proximal of the distal end of the cannula to the distal end of the cannula. This element is recited in independent claims 30 and 38 and is thus present in all

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claims. The claimed cannula thus has a structure that allows a guidewire to be moved laterally out of a guidewire lumen all the way to the distal end of the cannula. None of the cited references have such a structure. Additionally, the Examiner has not indicated what structure in any of the cited references would inherently allow such movement of the guidewire.

MPEP 2112 part IV states:

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)... "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Applicants submit that the Examiner has not provided a basis in fact and/or technical reasoning to reasonably support a determination that the devices of the cited prior art necessarily have structures that would allow a guidewire disposed in a lumen to be moved laterally out of the lumen from a first location proximal of the distal end to the distal end of the cannula, as is recited in the claims. The Examiner has thus not met the burden for showing inherency.

Additionally, the Examiner has not addressed Applicants' previous remarks and arguments regarding the above-described claim element. The following remarks and arguments were presented in the response filed December 22, 2005, and have not been addressed by the Examiner. If the rejection is maintained, Applicants respectfully request the Examiner provide a complete response to the following remarks and arguments.

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Applicants respectfully traverse the rejection. None of Kramer, Sirhan et al. or Euteneuer et al. teach a catheter having a lumen and guidewire lumen adapted to allow a guidewire disposed therein to be moved laterally out of the guidewire lumen from a first location proximal of the distal end of the cannula to the distal end of the cannula, as is recited in independent claims 30 and 38.

Kramer teaches "A second slit 24 is provide in the wall of the catheter body 11 which further defines the guidewire-receiving inner lumen and extends from the second guidewire port 17 to a location proximal to the proximal end 25 of the balloon 13." (emphasis added) See column 5, lines 28-32 and FIG. 1. Kramer thus does not teach a guidewire lumen adapted to allow a guidewire disposed therein to be moved laterally out of the lumen from a first location proximal of the distal end of a cannula to the distal end of the cannula, as is recited in the claims.

Sirhan et al. teach a catheter shaft where a "distal shaft section 21 is provided with distal slit 26 which extends from the proximal guidewire port 17 to a location 27 proximal to the proximal end of the balloon 13." (emphasis added) See column 6, lines 9-17 and FIG. 1. Sirhan et al. thus do not teach a guidewire lumen adapted to allow a guidewire disposed therein to be moved laterally out of the lumen from a first location proximal of the distal end of a cannula to the distal end of the cannula, as is recited in the claims.

Euteneuer et al. teach a tube with a longitudinally extending opening or slit 30 that communicates with insertion lumen 16, where "Slit 30 extends from proximal end 24 of tube 12 to end point 32, which is located near the proximal portion of inflation balloon 20." Euteneuer et al. also teach that "the distance D between distal tip 34 of catheter 10 and end point 32 of slit 30 is approximately ten inches." See column 3, lines 14-22 and FIG. 1. Euteneuer et al. thus teach

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away from a guidewire lumen being adapted to allow a guidewire to be moved laterally out of the lumen all the way to the distal end of the cannula, as is recited in the claims.

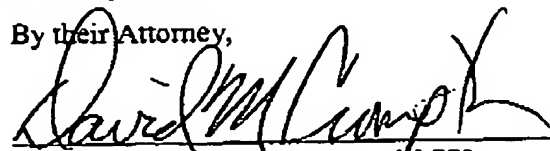
Ferguson et al. do not teach or suggest what Kramer, Sirhan et al. and Euteneuer et al. lack. Additionally, there is no motivation, suggestion, or guidance for one of ordinary skill in the art to modify any of Kramer, Sirhan et al. or Euteneuer et al. to achieve the claimed cannula. As stated above, each reference teaches a guidewire lumen allowing lateral movement of the guidewire only from a proximal portion up to a proximal end of a balloon on the catheter. Because each of Kramer, Sirhan et al. and Euteneuer et al. teach a balloon catheter, there is no reasonable expectation of success if one were to modify the references to allow the guidewire to move laterally out of the guidewire lumen all the way to the distal tip. Such a modification would destroy the balloon and thus destroy the function of the catheter system. Reconsideration and withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Mark Agro et al.

By their Attorney,



David M. Crompton, Reg. No. 36,772  
CROMPTON, SEAGER & TUFTE, LLC  
1221 Nicollet Avenue, Suite 800  
Minneapolis, MN 55403-2420  
Telephone: (612) 677-9050  
Facsimile: (612) 359-9349

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